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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,145	10/22/2003	Joseph Pilarski	P27,363 USA	4969
23307	7590	06/27/2005	EXAMINER	
SYNNESTVEDT & LECHNER, LLP			MALLARI, PATRICIA C	
2600 ARAMARK TOWER			ART UNIT	
1101 MARKET STREET			PAPER NUMBER	
PHILADELPHIA, PA 191072950			3736	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/691,145	<b>Applicant(s)</b> PILARSKI, JOSEPH	
	<b>Examiner</b> Patricia C. Mallari	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 9 and 12-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 10/23/02. It is noted, however, that applicant has not filed a certified copy of the Canadian application as required by 35 U.S.C. 119(b).

### ***Claim Objections***

Claims 1, 4, 6-9, 11-13, 18, and 19 are objected to because of the following informalities:

On line 2 of claim 1, "c)" should be replaced with "a)";

On line 5 of claim 1, "d)" should be replaced with "b)";

On lines 3-4 of claim 4, "the amount of sugar and rate of release of sugar in food in the subject" should be replaced with "an amount of sugar released and rate of release of sugar by food in the subject", since neither an amount of sugar nor "food in the subject" have been previously introduced and "the amount of sugar" recited here appears to refer to the amount of sugar released by food in the subject;

On lines 4-5 of claim 4, "the amount of sugar and rate of removal of sugar by insulin in the subject" should be replaced with "an amount of sugar removed and rate of removal of sugar by insulin in the subject" since neither an amount of sugar nor "insulin in the subject" have been previously introduced and "the amount of sugar" recited here appears to refer to the amount of sugar removed by insulin in the subject;

In claim 6, each of the step labels "a)" through "c)" should be replaced with "c)" through "e)"; to distinguish the steps from those in claim 1, upon which claim 6 ultimately depends;

On line 2 of claim 7, "standard" should be deleted, since the antecedent in claim 2 is "an intended food unit value" rather than an "intended standard food unit value";

In claim 8, each of the step labels "a)" through "c)" should be replaced with "c)" through "e)" to distinguish these steps from those in claim 1, upon which claim 8 ultimately depends;

On line 7 of claim 8, "b)" should be replaced with "d)";

On line 1 of claim 9, "the insulin" should be replaced with "insulin";

On line 1 of claim 11, "claim 1" should be replaced with "claim 2", since claim 2 recites "a food unit value" and claim 1 lacks such language;

On line 2 of claim 12, "standard" should be deleted, since the antecedent in claim 2 is "an intended food unit value" and not an "intended standard food unit value";

On line 1 of claim 12, "a time schedule" should be replaced with "a first time schedule";

On line 3 of claim 12, "a time schedule" should be replaced with "a second time schedule";

On line 1 of claim 13, "claim 2" should be replaced with "claim 12" since claim 12 recites "a time schedule" as recited on line 2 of claim 13, and claim 2 lacks such language;

On line 2 of claim 13, "the time schedule" should be replaced with "the first time schedule";

On line 1 of claim 16, "a)-c)" should be replaced with "c)-e)";

On line 2 of claim 16, "a)" should be replaced with "c)";

On line 3 of claim 16, "c)" should be replaced with "e)";

In claim 18, each of the step labels "a)" through "f)" should be replaced with "f)" through "l)", noting that there are two step f's in this claim;

In claim 19, each of the step labels "a)" through "g)" should be replaced with "f)" through "l)". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "the sugar metabolism resulting from the provided unit value" and "sugar metabolism resulting from the insulin units or food units" on lines 32-4 of the claim. It is unclear how sugar metabolism results from a value or a number of units of a substance.

Also, claim 3 recites determining the balance value based on "sugar metabolism resulting from the insulin units or food units". However, "the insulin units" in claim 3 appear to refer back to the "the balance value of either insulin units or carbohydrate

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units” on line 1 of part d) of claim 1, upon which claim 3 depends. Therefore, it is unclear how the balance value of the insulin or carbohydrate units may be determined based on a value resulting from itself.

Furthermore, the “food units” on lines 3-4 of claim 3 appears to refer back to “an intended food unit value” on line 2 of claim 2, wherein an intended food unit value is an intended carbohydrate value. It is unclear what the difference is between “sugar metabolism resulting from the provided unit value”, when the provided unit value is an intended carbohydrate unit value, and “sugar metabolism resulting from food units”, since food units are also described to be intended carbohydrate values.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,997,475 to Bortz. Bortz teaches a method of food and insulin dose management for a diabetic subject wherein an intended carbohydrate unit value is provided representing the amount of carbohydrate indeed for intake by the

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subject (col. 5, line 65-col. 6, line 5; col. 6, lines 26-43 of Bortz). The balance value of insulin units needed to balance with the provided unit value and maintain blood sugar in a target blood sugar range is determined (col. 6; lines 18-19 and lines 44-58 of Bortz).

Regarding claim 2, the intended carbohydrate unit value comprises an intended food unit value (col. 5, line 65-col. 6, line 5; col. 6, lines 26-43 of Bortz).

With further regard to claim 3, the balance value is calculated by determining for the subject a starting blood sugar value and comparing the sugar metabolism resulting from the provided unit value with sugar metabolism resulting from the insulin units recommended insulin dose, prior to consideration of the starting glucose level.

Regarding claim 7, while the reference fails to recite explicitly the steps of the subject receiving the intended food unit value and the subject receiving the recommended dosage of insulin, such steps are implied by the reference, since the method and device are shown to determine an amount of insulin to be administered by a user based upon the amount of carbohydrates ingested (col. 1, lines 54-58; col. 2, lines 41-47 of Bortz).

Regarding claim 10, the carbohydrate unit may comprise 15 g, wherein 15 g is about 16 g, of carbohydrate (col. 6, lines 31 of Bortz).

Regarding claim 11, the food unit may comprises toast including about 15 g, wherein 15 g is about 16 g, of carbohydrate (col. 4, line 3; col. 6, lines 29-31 of Bortz).

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2002/0107476 to Mann et al. Mann teaches a method of food and insulin dose management wherein an intended carbohydrate unit

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value representing the amount of carbohydrate intended for intake by the subject (paragraphs 0079, 0080, and 0087 of Mann). The balance value of insulin units needed to balance with the provided unit value and maintain blood sugar in the subject in a target blood sugar range, called "bolus" in the Mann reference, is determined (paragraphs 0079, 0080, 0082, 0083, & 0087 of Mann).

Regarding claims 2 and 3, the intended carbohydrate unit value comprises an intended food value (paragraphs 0079 and 0080 of Mann).

With further regard to claim 3, the balance value is calculated by determining for the subject a starting blood sugar value, called "CurrentBG" by the Mann reference, comparing the sugar metabolism resulting from the provided unit value with the sugar metabolism resulting from the insulin units, thereby calculating the amount of insulin units to maintain blood sugar in the subject in a target blood range (paragraph 0087 of Mann). To the best of the examiner's understanding (see rejection under 35 U.S.C. 112, 2<sup>nd</sup> paragraph set forth above), the sugar metabolism resulting from the provided unit value, when the provided unit value is a provided intended carbohydrate unit value, is merely the amount of carbohydrates to be consumed. Similarly, to the best of the examiner's understanding, the sugar metabolism resulting from the insulin units is merely the amount of carbohydrates covered or metabolized by a unit of insulin, or Carbohydrate Ratio.

Regarding claim 7, while the reference fails to recite explicitly the steps of the subject receiving the intended food unit value and the subject receiving the recommended dosage of insulin, such steps are implied by the reference, since the



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method and device are shown to determine an amount of insulin to be administered based upon the amount of carbohydrates ingested during a meal (paragraphs 0079 and 0080 of Mann)

***Allowable Subject Matter***

Claims 6, 8, 9 and 12-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4 & 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 4 and 5, the prior art of record fails to teach or fairly suggest a method of food and insulin dose management for a diabetic subject wherein the sugar metabolism resulting from the provided unit value and sugar metabolism resulting from the insulin units or food units are determined from the amount of sugar released and rate of release of sugar by food in the subject and the amount of sugar removed and the rate of removal of sugar by the insulin in the subject, in combination with all of the other limitations of the claims..

Regarding claims 6 and 16-18, the prior art of record fails to teach or fairly suggest a method of food and insulin dose management for a diabetic subject wherein

both a total sugar release value and a sugar release rate value are determined from the food unit value, in combination with all of the other limitations of the claims.

Regarding claims 8, 19, and 20, the prior art of record fails to teach or fairly suggest a method of food and insulin dose management for a diabetic subject wherein both a total sugar removal value to be removed from the blood of the subject and a sugar removal rate value are determined from the insulin unit value, in combination with all of the other limitations of the claims.

Regarding claim 9, the prior art of record fails to teach or fairly suggest a method of food and insulin dose management for a diabetic subject comprising the subject receiving insulin, insulin analog, or insulin mimetic in accordance with the intended insulin unit value and the subject receiving food containing a number of food units in accordance with the balance value, in combination with all of the other limitations of the claim.

Regarding claims 12-15, the prior art of record fails to teach or fairly suggest a method of food and insulin dose management for a diabetic subject comprising wherein the subject provides a time schedule for periodic, divided intake of the intended insulin unit value or the intended food unit value and the balance value is determined according to a time schedule for the subject to intake insulin units or food units needed to balance with the provided unit value and maintain blood sugar in the subject in the target blood sugar range during the time schedule. Note that it is assumed that claim 13 is intended to depend from claim 12 rather than claim 13, as stated above under "Claim Objections".

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication No. 2003/0040821 to Case;

US Patent No. 6,691,043 to Ribeiro, Jr.

US Patent No. 6,543,682 to Glaser

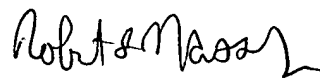
US Patent No. 5,216,597 to Beckers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia Mallari  
Patent Examiner  
Art Unit 3736

  
ROBERT MASS  
PATENT EXAMINER